K063589

3. 510(K) SUMMARY

1. Applicant/Sponsor: Gold Standard Orthopaedics, LLC.
   1226 Rowan St.
   Louisville, KY 40203

2. Contact Person: David Baughman
   President
   David06@Baughmangroup.com
   Phone (502) 581-8770

JAN 3 1 2007

3. Proprietary Name: GSO Bone Fixation Fasteners

4. Common Name: Bone Fixation Fasteners

5. Classification Name: Smooth or threaded metallic bone fixation fastener
   (21 CFR 888.3040)

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   - Sterile Kirschner Wires and Steinmann Pins – DePuy, Inc. (K960385)
   - PLUS Cancellous Bone Screws – Plus Orthopedics (K011719)
   - BTI Cortical Bone Screws – Biodynamic Technologies, Inc. (K972403)
   - IFS Cannulated Bone Screw – Internal Fixation Systems, Inc. (K061620)
   - OsteoMed 1.2mm Auto-Drive Screw System – OsteoMed Corp. (K023260)

7. Device Description:

   The GSO Bone Fixation Fasteners consist of sterile and non-sterile, single-use, smooth and threaded Kirschner wires and Steinmann pins (ranging in length from 4 to 12 inches and in diameter from 0.028 to 0.177 inches), and cortical, cancellous, and malleolar bone screws (ranging in length from 6 to 160 mm and in screw diameter from 1.5 to 6.5mm). All GSO Bone Fixation Fasteners are manufactured from 316-LVM stainless steel conforming to standard ASTM-F138.

8. Intended Use:

   The GSO Bone Fixation Fasteners are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

   ** Warning: GSO Bone Fixation Devices are not indicated for spinal fixation. **

9. Summary of Technologies/Substantial Equivalence:

   Every GSO Bone Fixation Fastener has the same intended use, similar design and the same indications for use as at least one of the following predicates: Sterile Kirschner Wires and Steinmann Pins – DePuy, Inc. (K960385), PLUS Cancellous Bone Screws – Plus Orthopedics (K011719), and BTI Cortical Bone Screws – Biodynamic Technologies, Inc. (K972403), OsteoMed 1.2mm Auto-Drive Screw System – OsteoMed Corporation (K023260). They are manufactured from the same material as the predicates: IFS Cannulated Bone Screw – Internal Fixation Systems, Inc. (K061620) and Sterile Kirschner Wires and Steinmann Pins – DePuy, Inc. (K960385).

10. Non-Clinical Testing:

    Non-clinical testing was not necessary to determine substantial equivalence between the GSO Bone Fixation Fasteners and the predicates.

11. Clinical Testing:

    Clinical testing was not necessary to determine substantial equivalence between the GSO Bone Fixation Fasteners and the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gold Standard Orthopaedics, L.L.C.
% Mr. David Baughman
President
1226 Rowan Street
Louisville, KY 40203

JAN 3 1 2007

Re: K063589
Trade/Device Name: GSO Bone Fixation Fasteners
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 16, 2006
Received: December 1, 2006

Dear Mr. Baughman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): N/A (unknown)

Device Name: GSO Bone Fixation Fasteners

Indications for Use:

The GSO Bone Fixation Fasteners are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

** Warning: GSO Bone Fixation Devices are not indicated for spinal fixation. **

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenn MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063589